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10/005,374	12/03/2001	Parker Small	UF-10488R	7033

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EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/005,374

**Applicant(s)**

SMALL ET AL.

**Examiner**

Stacy B. Chen

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 26, 2004 has been entered. This application has been transferred to examiner Stacy Chen, Art Unit 1648. Claims 1-40 are pending and under examination. Upon consideration of the claimed invention, new grounds of rejection are set forth below. Any inconvenience to Applicant for the delay in responding to the request for continued examination is regretted.
2. The rejection of claims 1-20 under 35 U.S.C. 112, first paragraph, for failing to comply with the enablement requirement is withdrawn. Applicant's arguments have been considered. The rejection is withdrawn because the claims are drawn to generic viral and bacterial vaccines, not specific species of organisms for which vaccines have not yet been discovered or enabled. The subject matter of the claims is the *dimensions of the particles* that deliver the vaccine, not the specific organism to be vaccinated against.
3. Note that claim 28 is missing a claim status identifier. Correction is required in future amendments in order to avoid a notice of non-compliance, thus further hindering prosecution. Claim 28 is objected to for a grammatical error, "particle's further comprise". This claim should read, "particles further comprise". Correction is required.

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4. Claim 1 and claims 10 recite units that are not consistent when referring to the tap density of the particles. It is suggested that the claims recite language that is consistent.

5. The abstract of the disclosure is objected to because there is a typo on line 7. Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 112***

6. Claims 21-40 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to methods of delivery of a vaccine to the pulmonary system, comprising administering the particles/vaccine to the respiratory tract of a patient, wherein the patient is vaccinated against a particular pathogen. As outlined in the previous final Office action of March 23, 2004, the specification does not provide any evidence that the delivery of the particles (along with the vaccine agent) is capable of entering the respiratory tract in such an amount or in such a way to provide protection against a pathogen. In order for the claims to be enabled for vaccination, animal model data with challenge experiments is required. Applicant has not demonstrated the ability of the claimed particles to reach their desired target in such a way as to remain effective as a vaccine.

Applicant's arguments have been considered, but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

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- Applicant argues that Attachment A, a simple study involving administration of a recombinant Modified Vaccinia Ankara MVA, is evidence that delivery of immunizing agents via the respiratory tract is a viable administration route for vaccines.
  - In response to this argument, the examiner has considered Attachment A. First, the experiments performed by Ethan Bender, a child, (Abstract for “Is Gator-Vax the End of the Flu”, were performed with a vaccine against influenza, administered intranasally to mice. The mouse animal model for humans with regard to influenza, is not sufficient to show efficacy because the issue is whether or not the *particles* can reach the lungs of a human in such a way that the human is protected from infection. Applicant needs to show evidence that particles attached to antigens are capable of protecting humans when administered via the pulmonary route.
- Applicant also argues that there is no logical or scientific basis to doubt that administration of particles with an immunizing agent known to effectuate a protective immune response would confer protective immunity when delivered in conjunction with biocompatible particles.
  - In response to this argument, the issue at hand is whether or not the *particles* can reach the lungs of a human in such a way that the human is protected from infection. When particles are combined with antigens, the physical properties of the antigens are altered in ways that must be accounted for when designing pulmonary vaccines. One of skill in the art would not expect that the

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administration of antigens alone is the same as administering antigens attached to carriers. Delivery of the particles attached to the antigens must be successful in order for the antigens to elicit a protective immune. Applicant has not demonstrated successful delivery of the particles attached to the antigens, nor has Applicant shown that the particles/antigens were delivered in a sufficient amount to induce a protective immune response in a human.

Therefore, claims 21-40 remain rejected for failing to meet the enablement requirements. The claims would be enabled for "inducing an immune response", if the language regarding protection, prophylaxis and treating is removed from the claims.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-40 are rejected under 35 U.S.C. 102(a) *and* 102(e) as being clearly anticipated by Edwards *et al.* (US 6,136,295, "Edwards", having priority to at least October 29, 1996). The claims are drawn to biocompatible particles for delivery of a vaccine to the pulmonary system comprising an immunizing agent, wherein the particles have a tap density less than 0.4 g/ml and

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at least 90% of the particles have geometric dimensions between about 5 microns and about 30 microns. The immunizing agent is selected from the group consisting of a live attenuated virus or bacterial vaccine, a recombinant virus or bacterial vaccine encoding an immunizing antigen or a combination of antigens against which elicitation of an immune response is desired, and an inactivated virus or bacterial vaccine. The particles have a mass mean diameter in the range of about 50 to about 100 microns. The particles are combined with a pharmaceutically acceptable carrier for administration to the respiratory tract. At least 90% of the particles have a mass mean diameter between about 5 and about 15 microns. At least 90% of the particles have a mean diameter between about 9 and about 11 microns. At least 50% of the particles have a tap density of less than  $0.1 \text{ g/cm}^3$ . The particles further comprise a polymeric or non-polymeric material in addition to the immunizing agent. Also claimed are methods of delivering the particles/antigens to a patient needing treatment, prophylaxis or diagnosis.

Edwards' patented claims (1-40) are nearly word for word verbatim with the instant claims that are drawn to various particle dimensions as products and for use in methods. The only difference between the two claim sets is that Edwards' claims are drawn to biocompatible particles for delivery of a *therapeutic, prophylactic or diagnostic agent* to the pulmonary system comprising a *therapeutic, prophylactic or diagnostic agent*. The instant claims are drawn to biocompatible particles for delivery of a *vaccine agent* to the pulmonary system comprising an *immunizing agent*. The terms, "prophylactic agent" and "vaccine agent" are synonymous. A prophylactic agent prevents disease, as does a vaccine agent. Edwards elaborates on the agents that are used, including proteins, peptides, antivirals, antigens and antibodies, for example

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(Edwards, col. 10). Therefore, the instant claims are clearly anticipated by Edwards' disclosure and Edwards' claims.

8. Claims 1-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards *et al.* (US 5,874,064, "Edwards '064", which is the parent application from which Edwards (above) is a divisional). It is noted that this reference was used in an obviousness rejection that was subsequently withdrawn. Upon further consideration of the reference and the instant claims, this reference is now applied as an anticipatory reference.

The claims are summarized above. Edwards '064 discloses biocompatible particles for delivery of a therapeutic, prophylactic or diagnostic agent to the pulmonary system comprising a therapeutic, prophylactic or diagnostic agent. Disclosed are particles dimensions (col. 4), particles density (col. 5), particle polymers (col. 6), particle polyesters (col. 7), and therapeutic and prophylactic agents (col. 10). The Edwards '064 patent discloses the use of a "prophylactic agent", while Applicant recites, "vaccine agent". These terms are synonymous because a prophylactic agent prevents disease, as does a vaccine agent. Therefore, the claims are clearly anticipated by Edwards '064.

9. Claims 1-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards *et al.* (WO 97/44013, "Edwards '97"). The claims are summarized above. Edwards '97 discloses aerodynamically light particles for pulmonary drug delivery, wherein the particles has a tap density of 0.4 g/ml and at least 90% of the particles have geometric dimensions between about 5 microns and about 30 microns (abstract, page 4-5, bridging paragraph and pages 7-9 in their

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entirety). The particles are formed of polymers, proteins, or polysaccharides (abstract and page 5, lines 4-17). Therapeutic agents include proteins, peptides, antibiotics, antivirals, antigens and antibodies (page 15, lines 10-32). Therefore, the instant claims are anticipated by Edwards '97.

### *Conclusion*

10. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen  
July 15, 2005